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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,904

01/16/2004

Eric J. Beckman

02-012

1518

29883 7590 09/13/2011
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/13/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/759,904	Applicant(s) BECKMAN ET AL.	
	Examiner JAMES ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3-69 and 104-116 is/are pending in the application.
- 5a) Of the above claim(s) 12-14,17,27-68,113 and 115 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3-11,15-16,18-26,69,104-112,114 and 116 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicants amendments to the claims filed 06/27/2011 have been entered. Any objection\rejections from the previous office action filed 04/01/2010 not addressed below has been withdrawn.

Election/Restrictions

Applicant's election with traverse of an extracellular matrix as the bioactive agent in the reply filed on 06/27/2011 is acknowledged. The traversal is on the ground(s) that there would be no serious search burden since it is applicant's belief that the examiner would essentially be searching for essentially the same art. This is not found persuasive because the species contain unrelated structures and each individual structure could require a separate individual search presenting an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-11,15-16,18-26,69 and 104-112,114 and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular the meets and bounds of the elected species extracellular matrix (ECM) as a bioactive agent capable of reacting with multifunctional isocyanate is unclear. An extracellular matrix is the part of animal tissue that provides support to animal cells and is the

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defining feature in connective tissue. The ECM is comprised of numerous components produced intracellularly by resident cells, essentially a soup of different components that molecularly include proteoglycans, heparin sulfate, keratin sulfate, hyaluronic acid, collagen, elastins, fibronectins and laminin and other components. Some of these components do contain reactive –OH or –NH₂ groups, thus the examiner does believe the claims are enabled. However given the breadth of the types of molecular components composed within ECM one of ordinary skill in the art could not ascertain the meets and bounds of the protection sought for the reactive components of ECM capable of reacting with a multifunctional isocyanate; rendering the claims indefinite. See http://en.wikipedia.org/wiki/Extracellular_matrix. For the purposes of examination the examiner will consider any component that may be found within an extracellular matrix as meeting the claimed reactant, including polyamino acids, proteins, fibronectins, heparin etc. To expedite the examination process the examiner notes that other species not elected such as virus, viral vector, anti-rejection agent and others while not elected may present additional 112 2nd indefinite issues.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-4,7-8,19,22,69,104-105,108 and 109,112,114 and 116 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the office action filed 11/30/2007.

Response to Arguments

Applicants argue in regards to Woodhouse that this reference does not teach reaction of an amine or an oligopeptide directly with a multi-functional isocyanate as presently claimed. Instead applicants contend the amines or oligopeptides are first reacted with another component via an esterification reaction as shown in figures A)-D).

The relevance of this assertion is unclear; Woodhouse clearly teaches reacting a diisocyanate with a polyol (claimed as additional ingredient in claim 4) and a chain extender that includes an amino acid oligopeptides, meeting the claimed bioactive agent. Figures A)-D) contain amino and OH groups, the very reactive groups claimed for the bioactive agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-11,15-16,18-26,69 and 104-112,114 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000)) or in view of Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the office action filed 11/30/2007.

Applicants assert Zhang teaches reaction of polyol with excess di-isocyanate in the absence of water to form a crosslinked prepolymer, in contrast to the claimed invention which requires water. Applicants assert Lipatova and Woodhouse do not cure this deficiency.

Applicants note at paragraph [0008] within their own specification that Zhang and coworkers used water as chain extenders for the prepolymers, Zhang also states that

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water is used as a chain extender within the abstract. Zhang is not deficient with respect to teaching water as a chain extender.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James W Rogers/

Examiner, Art Unit 1618